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No. 02-342

Supreme Court U.S.
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In The

Supreme Court of the United States

KEY PHARMACEUTICALS, SCHERING-PLOUGH CORPORATION AND SCHERING CORPORATION,

Petitioners,

v.

FREDERICK D. EDWARDS, M.D.,

Respondent.

On Petition For A Writ Of *Certiorari* To The Oregon Court Of Appeals

REPLY TO BRIEF IN OPPOSITION

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REPLY TO BRIEF IN OPPOSITION

Dr. Edwards' Opposition disputes neither the existence nor importance of the due process issues presented by this case. Rather, he primarily seeks to demonstrate that the alleged reprehensibility of Key's promotional conduct and its "gargantuan" size sufficiently justified the jury's duplicative and disproportionate punitive damages award. Dr. Edwards also claims that Key failed to protect its rights in the Oregon courts notwithstanding Key's undeniable assertions below that the punitive damages awarded to Dr. Edwards are unconstitutionally excessive and unconstitutionally tainted by the trial court's procedural mishandling of the *Mary Carter* issue.

The existence of evidence to justify an award of *some* punitive damages against Key is not disputed in the Petition, as it was not disputed in *Oberg*, *BMW*, or *State Farm*.[1] Rather, the Petition focuses on the standards for appellate review of the *amount* of such damages and the procedure by which they were awarded. If anything, Respondent's attempt to avoid these issues by explaining why and how the jury was persuaded to excess reinforces the constitutional infirmity of Oregon's rational juror review standard and the need for this Court to clarify and enforce its legal standards for reviewing and constraining punitive damages awards under the Fourteenth Amendment.

I. THE ADDITIONAL EVIDENCE SUMMARIZED IN THE OPPOSITION SUPPORTS ALLOWANCE OF THE WRIT.

Dr. Edwards' Opposition claims that the Petition for a Writ of *Certiorari* omits numerous "facts clearly material to consideration of the questions presented." Brief in

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[1] *Honda Motor Co., Ltd. v. Oberg*, 512 U.S. 415 (1994); *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *State Farm Mutual Auto Insurance Co. v. Campbell*, No. 01-1289 (*cert. granted* June 3, 2002).

Opposition ("Opposition") at 3-4. Dr. Edwards presents an extended counterstatement of facts that is intended to demonstrate that Key engaged in reprehensible conduct. Opp'n at 10. However, most of the conduct Dr. Edwards describes had nothing to do with the harm suffered by Plaintiff or Dr. Edwards, and has no bearing on whether this case merits a grant of *certiorari*.

The questions presented concern whether due process permits a state to impose multiple, cumulative punitive damages awards based on nationwide conduct, whether the rational juror standard of review is constitutionally adequate, and whether the procedure by which punitive damages were imposed satisfied due process. *See* Petition for a Writ of *Certiorari* ("Petition") at *i*. The fact that Key's conduct may have been sufficiently reprehensible to justify *some* punitive award does not override the protections of the Fourteenth Amendment. Moreover, the evidence that Dr. Edwards catalogues selectively – and, in Key's view, misleadingly – reinforces the overlap between the legal issues raised in the Petition and those raised by *State Farm*.

First, there is no causal link between most of the facts Dr. Edwards recites and Plaintiff's physical injury or Dr. Edwards' emotional injury. Thus, like *State Farm*, this case raises the issue whether due process guarantees permit a punitive damages award based on conduct unrelated to the plaintiff's injury. For example, Dr. Edwards describes at length the history of Key's revisions to its package insert to include a warning concerning the interaction of Ciprofloxacin and Theo-Dur.[2] It is

[2] Opp'n at 7. Dr. Edwards faults Key for failing to obtain quickly FDA approval to add a warning about the Ciprofloxacin interaction, and asserts that Key could have warned the medical community about the Ciprofloxacin interaction sooner than 1989. *Id.* However, Dr. Edwards undisputedly did not know when he treated Plaintiff that Plaintiff had been taking Ciprofloxacin. Tr. at 1295. No warning about the interaction, no matter its content or timing, could have affected Dr. Edwards' treatment of Plaintiff. Moreover, the Theo-Dur package insert and the

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undisputed, however, that Dr. Edwards had no knowledge that Plaintiff had been taking Ciprofloxacin and that, in any event, Dr. Edwards did not look at the warning label.

Similarly, Dr. Edwards' counterstatement of facts dwells extensively on an FDA Notice received by Key relating to Key's claims that Theo-Dur was superior to generic controlled release theophylline products.[3] Although a regulatory action such as the FDA Notice may be relevant to an assessment of Key's conduct, the FDA Notice plainly was not causally related to the injuries claimed. To the extent Key's punishment in this matter is based upon the Ciprofloxacin drug interaction evidence, or upon FDA's concerns with Key's marketing, this case clearly raises the legal issue raised by *State Farm* concerning the reliance of the Oregon courts on unrelated conduct.

Second, the theory of liability below was that Key's nationwide promotion of Theo-Dur had lulled doctors like Dr. Edwards into believing that Theo-Dur was safe and therefore caused them to ignore or fail to consult published warnings. Opp'n at 5-6.[4] Dr. Edwards and the lower courts

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Physician's Desk Reference ("PDR") Supplement included a Ciprofloxacin interaction warning at the time that Dr. Edwards treated Plaintiff. Trial Exs. 308, 318; Tr. 1309-10, 1408, 2486-87. Dr. Edwards did not consult either source. Thus, Key's market conduct concerning the Ciprofloxacin drug interaction clearly is not causally related to the injuries alleged by Plaintiff or Dr. Edwards.

[3] The January, 1989, FDA Notice faulted Key for claiming that Theo-Dur achieved "zero order absorption." Opp'n at 10; Trial Ex. 3. Dr. Edwards fails to note that Key fully satisfied the FDA's concerns simply by modifying its marketing materials to describe Theo-Dur as achieving "*apparent* zero order absorption." Tr. at 3392 (emphasis added). Dr. Edwards cannot plausibly contend that his treatment of Plaintiff was affected by Key's failure to include the adjective "apparent" in its promotional materials.

[4] Key does not challenge here the viability of Dr. Edwards' theory of liability. However, the idea that a treating physician can assert a belief that a prescription drug is "safe," ignores the fact that physicians act as the learned intermediary between the patient and the prescription drug manufacturer, *McEwen v. Ortho Pharmaceutical*

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alike have made it abundantly clear that the punitive damages awarded here are intended to punish and deter this nationwide conduct. Dr. Edwards clearly appealed to the jury to punish Key for all the actual and potential harms caused by or benefits obtained from this marketing campaign, whether or not those injuries arose in Oregon. As in *State Farm*, the question whether punitive damages may be based on extraterritorial conduct and consequences is squarely presented.

Dr. Edwards and Plaintiff persuaded the jury to impose massive punishment upon Key by arguing about the same conduct that is now the focus of Dr. Edwards' Opposition. Even if those facts were properly considered in evaluating the reprehensibility of Key's conduct – an issue that is before this Court in *State Farm* – they should not affect this Court's consideration of this Petition.

II. THE FEDERAL QUESTIONS RAISED IN KEY'S PETITION ARE PROPERLY PRESENTED.

Dr. Edwards argues, without citation to any authority, that none of the issues raised by Key are properly before this Court. He begins with the startling assertion that Key violated Rule 14.1(g). Opp'n at 12. In fact, Key fully complied with that rule in the section of the statement of the case entitled, "B. Presentation of Federal Questions." Pet. at 7-11. As that section demonstrates, Key raised the federal questions both at trial and on appeal, and clearly specified that the source of its objections was the Fourteenth Amendment.

The question of the constitutionality of the amount of the punitive damages award was raised and decided at every stage of this proceeding. As for the constitutionality of the trial procedure, Key argued both at trial and on

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Corp., 528 P.2d 522, 529 (Or. 1974), and that by definition, a prescription drug is safe and effective only when used in accordance with its labeling. 21 C.F.R. 310.303(a) (1977).

appeal that if the court tolerated the trial procedure set up by Plaintiff's and Dr. Edwards' pre-trial agreements, Key's due process rights to a fair trial would be implicated, causing error of constitutional dimension. The fact that no Oregon court chose to address this issue does not mean that the issue was not appropriately raised and preserved.

Certainly, it is essential to this Court's jurisdiction that a substantial federal question has been raised in the underlying state court proceedings. 28 U.S.C. § 1257(a). Meeting the jurisdictional requirements of § 1257(a) "does not demand the incantation of particular words; rather, it requires that the lower court be fairly put on notice as to the substance of the issue." *Nelson v. Adams USA, Inc.*, 529 U.S. 460, 469 (2000). It is sufficient if the record as a whole shows that the federal issue and grounds therefore were brought to the state court's attention. *New York ex rel. Bryant v. Zimmerman*, 278 U.S. 63, 67 (1928). Presentation of the issue in general rather than in precise terms also is sufficient. *Eddings v. Oklahoma*, 455 U.S. 104, 113 n.9 (1982). Once a federal claim is properly presented, a party is not limited on appeal to the precise arguments made below. *Harris Trust & Sav. Bank v. Salomon Smith Barney, Inc.*, 530 U.S. 238, 245 n.2 (2000); *Yee v. Escondido*, 503 U.S. 519, 534 (1992).

Generally, a federal question is deemed to be preserved if it was presented in a manner that satisfies the state rules governing preservation of issues. *Adams v. Robertson*, 520 U.S. 83, 86-87 (1997). In Oregon, "[f]or purposes of preserving an alleged error, raising an *issue* at trial ordinarily is essential, identifying a *source* for a claimed position is less so, and making a particular *argument* is least so." *Boytano v. Fritz*, 901 P.2d 835, 838 (Or. 1995), quoting *State v. Hitz*, 766 P.2d 373, 375 (Or. 1998) (emphasis in original); *see also Northwest Natural Gas Co. v. Chase Gardens*, 982 P.2d 1117, 1125 (Or. 1999) (appellate court's refusal to consider alternative causation arguments on appeal was error; "permitting [defendant] to make specific alternative arguments on appeal . . . results in no fundamental unfairness to [plaintiff]. . . . ").

The record clearly establishes both that Key expressly challenged the constitutionality of the punitive damages awarded to Dr. Edwards, and that the Oregon courts decided the issue adversely to Key. Pet. at 7-11; Opp'n at App. A. Dr. Edwards contends, however, that Key was required to raise below each argument supporting its contentions. Opp'n at 12-13.[5] This level of detail is not required. In fact, when this case was tried, this Court had yet to articulate the specifics of federal due process limits on awards of punitive damages. Neither *BMW* nor *Cooper Industries*[6] was yet decided. *BMW* was decided while *Bocci I* was before the Oregon Court of Appeals. In its reply brief below, Key discussed at length the standards and guideposts established in *BMW*, yet the Court of Appeals failed even to mention the case in its opinion. *Bocci v. Key Pharmaceuticals, Inc.*, 974 P.2d 758 (Or. Ct. App. 1999) (en banc) (per curiam) (12a-70a); *See Boytano*, 901 P.2d at 838 (error preserved when issue timely raised; newly available sources or arguments may be considered for first time on appeal).

Dr. Edwards also attempts to stand on the Court of Appeals' conclusion that Key failed to preserve a right to excessiveness review of the punitive damages award to Dr. Edwards. Opp'n at 20-21. As Key pointed out in footnote 10 of its Petition, the appellate court's *ipse dixit* conclusion is flatly contradicted by the record. Both at trial and on appeal, Key expressly challenged the constitutionality of

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[5] Dr. Edwards confuses federal questions with arguments made in support of those questions. Key raised only two federal questions for this Court's review, the first being the unconstitutional excessiveness of the punitive damages award to Dr. Edwards. Key cited three arguments in support of that federal question. To try to give teeth to his preservation argument, Dr. Edwards labels each of those arguments as a separate federal question. The law is clear, however, that a petitioner is not required to raise each argument below, but must only fairly raise the federal question at trial and on appeal. Key met this burden.

[6] *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001).

the punitive damages awarded to Dr. Edwards alone, and Dr. Edwards defended the amount of punitive damages awarded to him, never contending that Key had waived its right to claim that the award was unconstitutionally excessive. The appellate court simply wrongly refused to reach the issue. *See* Pet. at 10 n.10 (citing record). This in itself was constitutional error under the requirements of searching judicial review announced in *BMW* and *Cooper Industries*.

Similarly, Key expressly raised the issue of the unconstitutional impact of the trial procedure. Key argued that a state law trial procedure that allowed this tainted result violated federal due process guarantees. Pet. at 7-10. However, neither the trial nor appellate courts chose to address this issue. The fact that a state court does not address a federal issue does not mean that the issue was not fairly presented below. This Court's requirements are met *either* if the federal issue was raised in the state court *or* if it was considered and resolved by the state court. *See McGoldrick v. Compagnie Generale Transatlantique*, 309 U.S. 430, 434 (1940); *Hill v. California*, 401 U.S. 797, 805 (1971). A state court's refusal or failure to articulate its denial of a federal claim is just as reviewable as an express decision on the matter. *See Chambers v. Mississippi*, 410 U.S. 284, 290 n.3 (1973); *Street v. New York*, 394 U.S. 576, 581-85 (1969). Dr. Edwards has raised no other argument opposing *certiorari* with respect to the procedural due process issues raised by the Petition. In short, both of the federal questions raised in Key's Petition are properly before the Court, and warrant review.

III. RESPONDENT DOES NOT SERIOUSLY CHALLENGE THE IMPORTANCE OF THE QUESTIONS PRESENTED.

Aside from using an extended recitation of facts to deflect attention from the Petition's legal issues, Dr. Edwards' Opposition does not seriously dispute the importance of those legal issues. Dr. Edwards instead invites this court to follow the flawed approach taken by the

Oregon courts. The very arguments made by Dr. Edwards against review, however, illustrate the reasons this Court must step in to ensure against deprivation of property without due process of law.

First, Dr. Edwards wrongly contends that no issue of multiple, cumulative punitive damages awards is raised by this case. Opp'n at 17. Yet, Dr. Edwards acknowledges that Key was twice punished by conceding that the state's interest in punishing Key is "identical, whether the harmed party receiving the award is a patient or a physician." Opp'n at 19.[7] Dr. Edwards' assertions do not alter the fact that in this single case Key was punished with multiple, cumulative punitive damages awards, unique circumstances that make this an ideal vehicle through which to address these issues of multiple punishment.

The significance of this issue is highlighted by the *amicus* briefs of the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Product Liability Advisory Counsel, Inc. (PLAC). "Once a defendant has been fully punished for the effects of a given course of conduct, a second award based on the identical effects of the identical course of conduct necessarily exceeds the amount necessary to satisfy society's interest in punishment and deterrence." PhRMA Br. at 4. Repetitive awards "endanger the ability of future claimants to recover even basic compensatory damages," "pose[ ] a significant obstacle to global settlement negotiations . . . and block[ ] the ability of claimants to recover quickly for their injuries." PLAC Br. at 6-9.

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[7] Almost disingenuously, Dr. Edwards contends that the possibility of multiple cumulative damages is solved by the fact that a defendant can present evidence to the jury about other punishments imposed for the same conduct in different cases. Opp'n at 19. This response clearly demonstrates the significance of the issue presented. Here, the multiple, cumulative awards arose before a single jury, so there was no opportunity to present evidence that Key already had been punished.

Second, Dr. Edwards' sole substantive argument is that consideration of the reprehensibility of Key's conduct alone demonstrates a sufficient basis for the punitive damages award to Dr. Edwards. Opp'n at 20-21.[8] Dr. Edwards would have this Court ignore, as did the Oregon courts, the extreme disproportion of the compensatory damages to the punitive damages, and the obvious cumulative nature of the award. For example, Dr. Edwards argues that "nothing in this Court's decisions limits the proportionality review to whether there is a reasonable relationship between Dr. Edwards' punitive damages and his actual damages." Opp'n at 21. Yet *BMW* expressly requires courts to consider exactly the relationship Dr. Edwards eschews.

Dr. Edwards' Opposition also highlights another significant issue – whether the *BMW* guideposts are independent factors to consider in assessing the excessiveness of a punitive damages award. This Court has never addressed this issue, yet it is critical to the application of the *BMW* analysis. Had the Oregon court sought to apply each guidepost during its analysis, then it could not have allowed this staggering award of punitive damages.

Third, Dr. Edwards insists that this case raises no issue regarding the reliance on out-of-state conduct to justify a punitive damages award. As noted above, Dr. Edwards' reliance on Key's nationwide promotional activities and their potential nationwide effects raise just such an issue. *See also* Pet. at 20-22. Nor does Dr. Edwards dispute the significance of this unresolved issue.

Fourth, Dr. Edwards takes the position that Oregon's rational juror test does not conflict with this Court's

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[8] Dr. Edwards tries to explain away the comparative ratio of the award to Plaintiff and the award to Dr. Edwards by mentioning that the jury was limited to the amount of punitive damages demanded in the prayer for relief. As noted in the Petition, that amount is based on evidentiary support. Pet. at 6-7. Thus, the disparity between the two awards cannot be so easily avoided.

teachings in *Cooper Industries, BMW*, and *Oberg*.[9] Yet, as noted in the *amicus* briefs filed by the American Insurance Association (AIA) and the Associated Oregon Industries (AOI), Oregon's "rational juror" standard significantly erodes the searching review mandated by this Court's due process jurisprudence. Oregon's conflation of constitutional principles with state law factors has been repeated in many jurisdictions, diluting the *BMW* guideposts. *See* AIA Br. at 3, 7-11. Moreover, so long as Oregon's "rational juror" approach is permitted to stand, litigants will remain subject to a different standard of constitutional protection depending on where they are sued. *See, e.g.*, AOI Br. at 12-13.

CONCLUSION

For the foregoing reasons, the Court should grant the Petition for Writ of *Certiorari*.

Respectfully submitted,

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[9] Dr. Edwards claims that Key violated Rule 29.4(c) by failing to serve the Oregon Attorney General with its Petition, because Key's Petition allegedly draws into question the constitutionality of OR. REV. STAT. § 18.537(2) (1995). Dr. Edwards is wrong for two reasons. First, that statute was not in effect at the time of the trial, and thus is not implicated. Second, the statute simply codifies the rational juror standard previously articulated by the Oregon courts. That state law standard cannot supplant or override the searching review mandated by federal due process guarantees.